TECH CENTER 1600/2900

#9

PATENT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicants: J. Henslee, *et al.*

Serial No.: 09/975,502

Filed: October 11, 2001

For: REAGENTS AND METHODS USEFUL FOR DETECTING DISEASES OF THE BREAST

Case No.: 5972.US.P7

Group Art No.: 1645

Examiner: (not yet assigned)

Certificate of Mailing Under 37 C.F.R. §1.10(a)
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the:

Commissioner for Patents
Washington D.C. 20231

Kimberly A. Iorio 6-4-02

Kimberly A. Iorio Date

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington D.C. 20231

Prior to an examination of the above-referenced application on the merits, please amend the application as follows:

IN THE SPECIFICATION:

Please replace the BRIEF DESCRIPTION OF THE DRAWINGS section as originally filed (i.e., page 19, line 9 – page 21, line 3) with the following:

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 shows the binding curves of three of the monoclonal antibodies that recognized the recombinant polypeptide complex, produced in accordance with Example 7C.

FIGURE 2 shows the results of immunohistochemically staining two malignant breast sections, one normal breast section, and the HEK293-MB8 cell line with monoclonal antibody H9C65.

FIGURE 3 shows the results of immunohistochemically staining two malignant breast sections, one normal breast section, and the HEK293-MB8 cell line with monoclonal antibody J95C30.

FIGURE 4 is a scan of three Western blots showing three supernatants harvested from the growth of HEK293-MB8 cells. Blot 1 was developed with an anti-myc monoclonal antibody. Blot 2 was developed with an anti-BU101 polyclonal antisera. Blot 3 was developed with an anti-Mam polyclonal antisera.

FIGURE 5 is a scan of two dot blots showing immunorecognition of material by an anti-myc monoclonal antibody. The upper blot shows the fractions from supernatant of the MB8 cells eluting from a Nickel-chelation column. The lower blot shows the fractions from supernatant of the Mam M/H transient transfection of HEK293 cells eluting from a Nickel-chelation column.

FIGURE 6 is a scan of 4 Western blots comprising 16 panels. Supernatants from the MB8 cells and the transient transfection of HEK293 cells with Mam M/H plasmid are analysed by anti-BU101, anti-Mam, and anti-myc polyclonal and monoclonal antibodies.

FIGURE 7 is a scan of a Western blot from an isoelectric focusing gel (pH 3-10).

FIGURE 8 is a scan of 2 dot blots showing immunorecognition of material by an anti-myc monoclonal antibody. The upper blot shows the fractions from supernatant of the MB8 cells eluting from a Mono Q 5/5 column. The lower blot shows the fractions from supernatant of the Mam M/H transient transfection of HEK293 cells eluting from a Mono Q 5/5 column.

FIGURE 9 is a standard curve for a Superose 12 column showing the relationship between elution volume and molecular weight of protein standards.

FIGURE 10 is a scan of a dot Blot showing immunorecognition of material by an anti-myc monoclonal antibody. The blot shows the fractions from supernatant of the MB8 cells eluting from a Superose 12 column.

FIGURE 11 is a scan of 2 Western blots analysing two tissue extracts and two supernatants with recombinant myc-his tagged Mam and BU101. The upper blot was developed with an anti-BU101 monoclonal antibody and the lower blot was developed with an anti-Mam polyclonal antibody.

FIGURE 12 is a scan of 2 dot blots showing immunorecognition of material by an anti-BU101 polyclonal antibody (upper blot) or an anti-Mam polyclonal antibody (lower blot). Both blots represent the fractions from a breast cancer tissue extract eluting from a Mono Q 5/5 column.

FIGURE 13 is a scan of 2 Western blots showing immunorecognition of material by an anti-BU101 polyclonal antibody (upper blot) or an anti-Mam polyclonal antibody (lower blot). Both blots represent the fractions from a breast cancer tissue extract eluting from a Mono Q 5/5 column.

FIGURE 14 is a scan of 2 dot blots showing immunorecognition of material by an anti-BU101 polyclonal antibody (upper blot) or an anti-Mam polyclonal antibody (lower blot). Both blots represent the fractions from a breast cancer tissue extract eluting from a Superose 12 column.

FIGURE 15 is a scan of a dot blot showing enhanced immunorecognition of myc-his tagged polypeptides using pretreatment protocols.

FIGURE 16 is the BU101 amino acid sequence.

FIGURE 17 is the assembly of BS106 from individual expressed tags.

FIGURE 18A is the BS106 polynucleotide sequence (SEQ ID NO:7) and 18B is the BS106 polypeptide sequence (SEQ ID NO:8).

FIGURE 19A, 19B AND 19C show the relative expression of BU101, mammaglobin and BS106, respectively.

FIGURE 20 A-D show BU101 complexing with mammaglobin.

FIGURE 21 shows correlation between marker expression and clinical and molecular parameters.

REMARKS

Consideration and allowance of the above-referenced application are respectfully requested.

The changes made the Brief Description of the Drawings section relate to sequence identifier additions and grammatical changes and do not represent new subject matter.

It is believed that the subject application is in condition for allowance and Notice to that effect is respectfully requested.

Should the Examiner have any questions concerning the above, he or she is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,
J. Henslee, et al.

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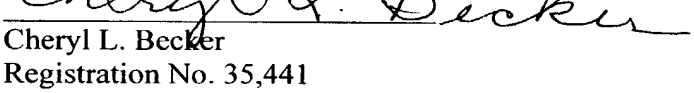
ABBOTT LABORATORIES
Telephone: (847) 935-1729
Facsimile: (847) 938-2623



Cheryl L. Becker
Registration No. 35,441
Attorney for Applicants

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please amend the subject application as follows:

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BRIEF DESCRIPTION OF THE DRAWINGS

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FIGURE 17 is the assembly of BS106 from individual expressed tags.

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FIGURE 19A, 19B and 19C [shows] show the relative expression of BU101, mammaglobin and BS106, respectively.

FIGURE 20 A-D [shows] show BU101 complexing with mammaglobin.

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